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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,871	12/14/2006	Francis Gigliotti	176/61732	7743

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,871	GIGLIOTTI ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,20,24,25,28-35,37-43,45-50,52-61 and 64-88* is/are pending in the application.

4a) Of the above claim(s) *20,24,25,28-35,37-43,45-50,52-61 and 64-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *010708*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicants' preliminary amendments filed 06/29/06 and 04/26/07.

Election

2) Acknowledgment is made of Applicants' election filed 08/27/09 in response to the lack of unity mailed 04/01/09. Applicants have elected invention I, claims 1-12, and the A12 clone polypeptide species of *Pneumocystis carinii*, without traverse.

Status of Claims

3) Claims 13-19, 21-23, 26, 27, 36, 44, 51, 62 and 63 have been canceled via the amendment filed 06/29/06.

Claims 1-12, 20, 24, 25, 28-35, 37-43, 45-50, 52-61 and 64-88 are pending.

Claims 20, 24, 25, 28-35, 37-43, 45-50, 52-61 and 64-88 are withdrawn from consideration as being directed to a non-elected invention and/or species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1-12 are under examination. A First Action on the Merits on these claims is issued.

Information Disclosure Statement

4) Acknowledgment is made of Applicants' Information Disclosure Statement filed 01/07/08. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Sequence Listing

5) Acknowledgment is made of Applicants' submission of the sequence listing and CRF which have been entered on 06/06/07.

Priority

6) The instant application is the national stage 371 application of the international application, PCT/US2004/43959, filed 12/31/04 and claims priority to the provisional application 60/533,788 filed 12/31/03.

Objection(s) to Specification

7) The specification is objected to for the following reason(s):

The use of the trademarks has been noted in this application. For example, see paragraph [0129] for 'Reactigel'. The trademark recitation should be capitalized. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification and make necessary changes wherever trademark recitations appear.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

8) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

9) Claims 1-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Instant claims are vague and indefinite in the limitation: 'protein or polypeptide' (see line 1) because it is unclear how one differs from the other in terms of scope, size, or length.

(b) Claim 1 is indefinite, inconsistent and confusing in the limitation: 'the isolated *polypeptide* is not a ..... *protein*' [Emphasis added]. See last the two lines. The metes and bounds of the claim are indeterminate.

(c) Claims 2, 3 and 5-11 are indefinite because the claims lack proper antecedent basis in the limitation: 'polypeptide' (see lines 1 and 2). Instant claims depend from claim 1 which already includes the limitation of an isolated polypeptide. For proper antecedent basis, it is suggested that Applicants provide proper antecedent basis to the above-identified limitation by replacing it with the limitation --the polypeptide--.

(d) Analogous rejection and criticism apply to claims 4 and 12.

(e) Claim 2 is vague and indefinite in the limitation 'a Pneumocystis kexin'. Claim 2 depends from claim 1 which includes the limitation 'a full-length Pneumocystis kexin'. Is 'a Pneumocystis kexin' recited in claim 2 different from the one recited in claim 1? If not, it is suggested that Applicants provide proper antecedent basis to the limitation.

(f) Claim 3 is vague and indefinite in the limitation 'Streptococcus pneumoniae PspA'. Claim 3 depends from claim 1 which includes the limitation 'a full-length Streptococcus pneumoniae PspA'. Is 'Streptococcus pneumoniae PspA' recited in claim 3 different from the one recited in claim 1? If not, it is suggested that Applicants provide proper antecedent basis to the limitation.

(g) Claim 4 is vague and indefinite in the abbreviated limitation: 'SSC', because it is unclear what does this limitation encompass. It is suggested that the abbreviation be recited as a full terminology, with its abbreviated recitation retained therein in parentheses.

(h) Claim 5 is vague, indefinite and confusing in the limitation: 'clone A12 of Pneumocystis carinii'. Claims 5 depends from claim 4, which includes the limitation 'encoded by .... the nucleotide sequence .... of the Pneumocystis A12 clone'. Is the 'clone A12 of Pneumocystis carinii' recited in claim 5 a protein or a polypeptide, or a nucleic acid molecule that encodes the protein or the polypeptide?

(i) Claims 2-12, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C § 102

10) The following is a quotation of the appropriate paragraph(s) of 35 U.S.C. § 102 that form the basis for the rejection(s) under this section made in this Office action:

> A person shall be entitled to a patent unless –
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11) Claims 1-8 and 12 are rejected under 35 U.S.C § 102(b) as being anticipated by WO 98/39424 (ISIS INNOVATION LIMITED – Applicants' IDS).

ISIS INNOVATION LIMITED taught an isolated protein or polypeptide antigenic portion, Lam-1, comprising a proline-rich domain comprising the proline-rich amino acid

sequence QPEPQPEP, i.e., the instantly recited SEQ ID NO: 1. The purified protein or the polypeptide domain was used to generate an immune response or antibodies using injection with Freund's adjuvant (i.e., pharmaceutically acceptable carrier). One protein or polypeptide antigenic portion comprises from Pro641 to Pro707 of PRT1 of *Pneumocystis carinii*. The prior art polypeptide is not a full length pneumococcal PspA or *Pneumocystis* kexin protein or polypeptide, but a proline-rich region, a part, or a domain of the PRT1 protein or polypeptide, and therefore, qualifies as a fragment of a pneumooccal PspA or *Pneumocystis* kexin protein or polypeptide that comprises the amino acid sequence QPEPQPEP. See the last line in Figure 4 on page 11/21; last full paragraph on page 45; claims 7, 10 and 11; first full paragraph on page 12; paragraph bridging pages 7 and 8; pages 7 and 5; top of page 28; and pages 33, 35 and 38. The use of the prior art protein or polypeptide region or its analogues as vaccines and therapeutic agents is taught. See pages 8 and 9. Figure 7 depicts fragments of recombinantly expressed PRT1. The proline-rich region contained the tetrapeptides Pro-Glu-Pro-Gln and Pro-Glu-Thr-Gln and its length varied from approximately 67 amino acid residues in the shortest sequence and 233 residues in the longest sequence, i.e., less than 600, 300, or 100 amino acids in length. See the full paragraph on page 19. Since the prior art sequence and the instantly claimed sequence are the same structurally, the prior art protein or polypeptide antigenic portion is expected to be necessarily encoded by a nucleic acid molecule that hybridizes to the nucleotide sequence of 1-837 of the A12 clone of *Pneumocystis carinii*.

Claims 1-8 and 12 are anticipated by ISIS INNOVATION LIMITED.

Rejection(s) under 35 U.S.C § 103

12) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

13) Claims 9 and 10 are rejected under 35 U.S.C § 103(a) as being unpatentable over WO 98/39424 (ISIS INNOVATION LIMITED – Applicants' IDS) as applied to claim1 above.

The teachings of the ISIS INNOVATION LIMITED is explained above, which do not expressly state the length of the isolated protein or polypeptide antigenic portion is less than 50 or 25 amino acids in length.

However, it was routine and conventional in the art at the time of the invention to produce shorter peptides of desired size such as fifteen-mer peptides by incorporating art-known polypeptide domains or epitopes to raise polyclonal antibodies to such peptides. For example, ISIS INNOVATION LIMITED taught the production of fifteen-mer peptides of their protein for the purpose of raising polyclonal antisera to the peptides. See pages 32 and 33.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce a proline-rich domain peptide comprising the prior art proline-rich amino acid sequence QPEPQPPQP or QPEPQPEP to produce the instant invention. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of raising polyclonal antibodies to the proline-rich amino acid sequence QPEPQPPQP or QPEPQPEP.

Claims 9 and 10 are *prima facie* obvious over the prior art of record.

14) Claim 11 is rejected under 35 U.S.C § 103(a) as being unpatentable over WO 98/39424 (ISIS INNOVATION LIMITED – Applicants' IDS) as applied to claim1 above and further in view of Mann *et al*. (US 6,165,469).

The teachings of the ISIS INNOVATION LIMITED is explained above, which do not expressly state that the isolated protein or polypeptide antigenic portion is present in a number more than 1.

However, it was routine and conventional in the art at the time of the invention to include multiple copies of a given art-known single molecule, small peptide, or an epitope to produce a

single fusion protein for the purpose of enhancing the immunogenicity of said single small peptide or epitope. For example, Mann *et al*. provided such a teaching. See first full paragraph in column 11.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce a fusion polypeptide by including two or more copies of the proline-rich domain peptide comprising the prior art proline-rich amino acid sequence QPEPQPEP to produce the instant invention. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of enhancing the immunogenicity of the prior art proline-rich amino acid sequence QPEPQPEP since such a process was known to enhance the immunogenicity of a single small peptide or epitope as taught by Mann *et al*.

Claim 11 is *prima facie* obvious over the prior art of record.

Claim Objection(s)

15) Claims 1-5 are objected for not italicizing the names of the bacteria recited therein: 'Streptococcus pneumoniae', 'Pneumocystis carinii', or 'Pneumocystis'.

Remarks

16) Claims 1-12 stand rejected.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

18) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday

to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

November, 2009